

# Exhibit 14

UNITED STATES  
 SECURITIES AND EXCHANGE COMMISSION  
 Washington, D.C. 20549  
 FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS  
 PURSUANT TO SECTION 13 OR 15(D) OF THE  
 SECURITIES EXCHANGE ACT OF 1934

(Mark One)  
 ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT  
 OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2000  
 OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (D) OF THE SECURITIES  
 EXCHANGE ACT OF 1934

For the Transition Period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 1-9898

Organogenesis Inc.  
 (Exact name of registrant as specified in its charter)

DELAWARE 04-2871690  
 (State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

150 DAN ROAD, CANTON, MA 02021  
 (Address of principal executive offices) (Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (781) 575-0775

SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT:  
 Name of Each Exchange

Title of Each Class	ON WHICH REGISTERED
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Common Stock, \$.01 value	American Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ( X ) No ( )

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ( )

The approximate aggregate market value of voting stock held by non-affiliates of the registrant was \$319,917,000 based on the last reported sale price of the company's common stock on the American Stock Exchange as the close of business on March 19, 2001. There were 34,399,675 shares of common stock outstanding as of March 19, 2001, excluding treasury shares.

DOCUMENTS INCORPORATED BY REFERENCE

PART OF FORM 10-K  
 into which  
 INCORPORATED

Document

Portions of the Registrant's Definitive Proxy Statement  
 for its 2001 Annual Meeting of Stockholders..... III

With the exception of the portions of the Definitive Proxy Statement for the registrant's 2001 Annual Meeting of Stockholders expressly incorporated into this Report by reference, such document shall not be deemed filed as a part of this Annual Report on Form 10-K.

## PART I

This Form 10-K contains forward-looking statements that involve risks and uncertainties. Forward-looking statements include information on:

- Our business outlook and future financial performance;
- Anticipated profitability, revenues, expenses and capital expenditures;
- Anticipated research, development, clinical, regulatory, and reimbursement progress;
- Future funding and expectations as to any future events; and
- Other statements that are not historical fact and are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties.

Although we believe that our plans, intentions and expectations reflected in or suggested by such forward-looking statements are reasonable, we can give no assurance that such plans, intentions or expectations will be achieved. When considering such forward-looking statements, you should keep in mind the risk factors and other cautionary statements in this Form 10-K. The risk and other factors noted under the section "Risk factors" beginning on page 5 and throughout this Form 10-K could cause our actual results to differ materially from the results contained in any forward-looking statements.

## ITEM 1. BUSINESS

Organogenesis Inc. - a tissue engineering company - designs, develops and manufactures medical products containing living cells and/or natural connective tissue. We are the developer and manufacturer of the only mass-produced product containing living human cells to gain Food and Drug Administration ("FDA") marketing approval. Our product development focus includes living tissue replacements, a cell-based organ assist device and other tissue-engineered products. Our lead product, Apligraf living skin substitute, is FDA approved and marketed for use in the treatment of diabetic foot ulcers and venous leg ulcers. Novartis Pharma AG ("Novartis") has exclusive global Apligraf marketing rights.

Organogenesis was organized as a Delaware corporation in 1985. Our principal office is located at 150 Dan Road, Canton, Massachusetts 02021. The telephone number is 781/575-0775 and the fax number is 781/575-1570. Our website address is [www.organogenesis.com](http://www.organogenesis.com).

## PRODUCTS AND PROGRAMS

Organogenesis is utilizing its expertise in living cells and connective tissue in its product development. In addition to Apligraf, major programs include a living dermal replacement product candidate Vitrix(TM), a coronary vascular graft and a liver assist device. These programs are profiled on the following pages.

Apligraf(R) is a registered trademark of Novartis.  
Vitrix(TM) is a trademark of Organogenesis.

## ON THE MARKET - APLIGRAF

Product Description - Apligraf is the only mass-produced product containing living human cells to gain FDA marketing approval. Apligraf contains living human skin cells - keratinocytes and fibroblasts - organized in an epidermal and dermal layer. Apligraf is mass-produced, available to physicians on demand and does not require hospitalization for use.

[IMAGE APPEARS HERE]

Apligraf compared to human skin under the microscope

Status - Novartis Pharma AG has exclusive global Apligraf marketing rights. The 2001 amendment to our 1996 agreement with Novartis significantly increases payments we receive for Apligraf units, as well as provides funding support for certain facility investments, clinical development activities and up to \$20,000,000 in equity investments. Apligraf gained FDA marketing approval for use in the treatment of venous leg ulcers in 1998. In June 2000, Apligraf was also approved in the US for use in the treatment of diabetic foot ulcers. Apligraf is on the market in select international markets. It is anticipated that Novartis will submit for marketing approval across the European Union in Spring 2001.

Current and Potential Markets -

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Diabetic foot ulcers: Apligraf is FDA-approved for use in the treatment of healing-resistant diabetic foot ulcers. Apligraf has been shown to heal more of these ulcers, and heal them faster, than standard care alone. A common complication of diabetes, foot ulcers afflict up to 800,000 people in the US. Unhealed, these wounds can lead to life-threatening infections. They result in over 50,000 amputations per year. Foot ulcers are also a leading cause of hospitalization among diabetics. These wounds are estimated to cost the US healthcare system over \$1 billion per year.

Venous leg ulcers: Apligraf is also approved and marketed in the US for the treatment of healing-resistant venous leg ulcers, chronic wounds caused by poor blood circulation. Apligraf has also been shown to heal more of these ulcers, and heal them faster, than standard care alone. Similar in incidence to diabetic foot ulcers, venous ulcers can take six months or longer to heal. Data on the cost-effectiveness of Apligraf in the treatment of hard-to-heal venous leg ulcers were published during 2000.

Skin surgery wounds: For skin surgery wounds, there is a need to improve the quality of healing, such as reducing scarring. We currently have a pivotal trial underway to assess the ability of Apligraf to reduce scarring following skin cancer surgery. We expect to complete this trial and submit to the FDA for marketing approval within the next twelve months.

Other potential markets: As a skin substitute, Apligraf has a number of additional potential uses, including pressure ulcers, burns, epidermolysis bullosa (a genetic skin disorder), and other chronic and acute wounds.

Reimbursement - In Summer 2000, Apligraf was placed on the Outpatient Prospective Payment System list by the Health Care Financing Agency (HCFA). This qualified the product for reimbursement by Medicare when applied in the hospital outpatient setting, such as hospital-affiliated wound care clinics. In February 2001, Apligraf was classified by HCFA as a biologic for reimbursement purposes when used in a doctor's office. This supports the development of local reimbursement policies for Apligraf by the 42 local administrators of Medicare. We expect some regions to begin reimbursing Apligraf within the next few quarters and anticipate many regions will begin reimbursing Apligraf within the next twelve months.

#### LIVING DERMAL REPLACEMENT PRODUCTS

Deep wounds involve loss of dermis, the skin's lower layer. Dermal tissue contributes to wound healing. It also plays an important role in healing quality. Because dermal tissue, once lost, is not regenerated by the body, a need exists for living dermal replacement products.

Our lead living dermal replacement product candidate is Vitrix. Vitrix is a single layer product containing living human dermal cells (fibroblasts) and dermal structural protein (collagen). Because Vitrix is a single dermal layer, it can be folded upon itself and inserted into deep wounds. Potential applications for Vitrix include deep diabetic foot ulcers and deep pressure sores, such as those extending through skin to underlying bone, ligament or tendon. We expect to begin human pivotal trials with Vitrix in Spring 2001. The 2001 amendment to the 1996 agreement with Novartis grants Novartis the right to purchase an exclusive option to negotiate terms to license Vitrix, as well as a second living dermal replacement product currently in research.

#### CORONARY VASCULAR GRAFT

Our coronary vascular graft, currently in animal trials, is being developed for use in coronary artery bypass grafting (CABG) procedures. Approximately 350,000 CABG procedures are performed annually in the US. These procedures are performed to channel blood around blockages in the arteries that keep the heart alive. CABG procedures typically require several grafts as patients generally have multiple blockages. The primary material used for bypass grafts is vein harvested from the patient's leg. Unfortunately, the patient may not have sufficient vein available. Additionally, use of a patient's vein adds to the surgical complexity and, thus, cost of the procedure, as well as increases the risk of post-surgery complications.

Our vascular graft is designed to be an off-the-shelf product, available upon demand, which would replace the need to use patient vein for grafting material. As inclusion of living blood vessel cells would cause rejection, our vascular graft does not contain cells when implanted. It is designed to become populated with the patient's own cells after implantation. In 1999, we published data showing that, in small animals, our product performs the critical functions: it maintains blood flow over time and becomes converted into living tissue. During 2000, our program focused on tightening the design of the product and enhancing the reliability of its manufacturing process in preparation for initiating studies in large animals and then humans.

#### LIVER ASSIST DEVICE

Each year in the US, approximately 300,000 people are hospitalized for liver disease and over 25,000 die from liver failure. Our liver assist device is being developed as a "bridge to transplant" to keep a patient alive until a donor liver becomes available. The device could also be used in some situations as an alternative to transplantation, keeping a patient alive for the few weeks needed for his or her own liver to recover. This would be beneficial as liver transplantation is risky, invasive and expensive and typically requires lifelong immunosuppressant drug therapy.

Our goal in 2001 is to develop a prototype that demonstrates significant efficacy in large animal models. In 1999, we received a \$2 million award under the Advanced Technology Program of the National Institute for Standards and Technology to assist us in achieving that goal.

#### OTHER POTENTIAL OPPORTUNITIES

During 2000, Organogenesis formed a business unit - Technology Ventures - to commercialize, through partnerships and distributorships, our engineered collagen and conditioned medium technologies. During the first half of 2001, the business unit plans to submit for FDA 510(k) marketing clearance of the engineered collagen for several different uses. Technology Ventures has established a collaboration with privately-held Royce(R) Medical Co. That collaboration is for commercialization of the engineered collagen technology as a wound dressing to certain targeted audiences. We expect to begin that commercialization during the second half of 2001. Our goal is to establish additional collaborations for both the engineered collagen and conditioned medium technologies.

#### RISK FACTORS

##### OUR COMPANY HAS A HISTORY OF LOSSES AND WE EXPECT TO CONTINUE TO INCUR LOSSES

Organogenesis Inc. was founded in 1985. We have incurred operating losses in every year of our existence. We incurred net losses of \$14,031,000 for the year ended December 31, 1998, \$28,350,000 for the year ended December 31, 1999 and \$28,605,000 for the year ended December 31, 2000, which losses are continuing. As of December 31, 2000, we have an accumulated deficit of \$157,972,000. We have not achieved profitability and expect to continue to incur net losses through at least the first half of 2002. The extent of future losses and the time required to achieve profitability is highly uncertain. Moreover, although our business is not seasonal in nature, our revenues have historically varied significantly from fiscal quarter to fiscal quarter due to the recognition of non-refundable research, development and milestone payments.

##### IN ORDER TO ACHIEVE COMMERCIAL SUCCESS, OUR PRODUCTS MUST GAIN MARKET ACCEPTANCE

We have one principal product on the market, Apligraf, which is marketed by Novartis. Products under development, as well as additional uses for Apligraf, will require additional research and development efforts, including clinical testing and regulatory approval, prior to commercial use. Our potential products are subject to the risks of failure inherent in the development of medical products based on new technologies. These risks include the possibilities that:

- Our approach will not be successful;
- Our potential products will be found to be unsafe, ineffective or otherwise will fail to meet applicable regulatory standards or receive necessary regulatory clearances;
- The potential products, if safe and effective, will be difficult to develop into commercially-viable products, will be difficult to manufacture on a large scale, will be uneconomical to market, will fail or be delayed in gaining acceptable insurance reimbursement or will fail to obtain acceptance by the medical community;
- Proprietary rights of third parties will preclude us from marketing such products; or
- Third parties will market superior or equivalent products.

Our business results would be hurt if we are unable to demonstrate to the medical community the efficacy, relative safety and cost-effectiveness of treating patients with our products or if our products were not accepted as alternatives to other existing or new therapies.

OUR MARKETS ARE COMPETITIVE AND OUR COMPETITORS COULD DEVELOP MORE EFFECTIVE PRODUCTS

We are engaged in the rapidly evolving and competitive field of tissue engineering for the treatment of skin wounds and other medical needs. Our competitors include tissue engineering companies, xenotransplant companies, wound care divisions of major pharmaceutical companies and other pharmaceutical, biotechnology and medical products companies using traditional technologies to develop products for wound care. Some of these companies have much greater resources, research and development staffs and facilities, experience in conducting clinical trials and obtaining regulatory approvals and experience in the manufacturing, marketing and distribution of products than we do. Our competitive position is based upon our ability to:

- create and maintain scientifically-advanced technology and proprietary products and processes;
- attract and retain qualified personnel;
- obtain patent or other protection for our products and processes;
- obtain required government approvals on a timely basis;
- manufacture products on a cost-effective basis; and
- successfully market products.

If we are not successful in meeting these goals, our business could be hurt. Similarly, our competitors may succeed in developing technologies, products or procedures that are more effective than any that we are developing or that would render our technology and products obsolete, noncompetitive or uneconomical.

WE CURRENTLY DEPEND UPON NOVARTIS TO MARKET APLIGRAF AND NOVARTIS MAY NOT BE SUCCESSFUL IN MARKETING APLIGRAF IN THE FUTURE

We currently have limited experience in sales, marketing and distribution and have developed a long-term strategic relationship with Novartis, who has marketing and sales forces with technical expertise and distribution capability. Our revenues will depend upon the efforts of Novartis, who may or may not be successful in marketing and selling Apligraf or gaining international approvals for the product. We may not be able to maintain our long-term strategic relationship with Novartis. To the extent that we choose not to maintain our relationship with Novartis, we may need more capital and resources to undertake a commercialization program at our own expense. In addition, we may encounter significant delays in introducing Apligraf into certain markets or find that the commercialization of Apligraf in such markets may be adversely affected by the absence of a collaborative agreement.

OUR ABILITY TO COMMERCIALIZE OUR PRODUCTS DEPENDS UPON OUR COMPLIANCE WITH GOVERNMENT REGULATIONS

Our present and proposed activities are subject to extensive and rigorous regulation by governmental authorities in the US and other countries. To clinically test, produce and market medical devices for human use, we must satisfy mandatory procedural and safety and efficacy requirements established by the FDA and comparable state and foreign regulatory agencies. Typically, such rules require that products be approved by the government agency as safe and effective for their intended use prior to being marketed. The approval process is expensive, time consuming and subject to unanticipated delays. Our product candidates may not be approved. In addition, our product approvals could be withdrawn for failure to comply with regulatory standards or due to unforeseen problems after the product's marketing approval.

Testing is necessary to determine safety and efficacy before a submission may be filed with the FDA to obtain authorization to market regulated products. In addition, the FDA imposes various requirements on manufacturers and sellers of products under its jurisdiction, such as labeling, Good Manufacturing Practices, record keeping and reporting requirements. The FDA also may require post-marketing testing and surveillance programs to monitor a product's effects. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals or could negatively affect the marketing of our existing products. We would not be able to commercialize our products as planned and our operating results would be hurt if:

- the regulatory agencies find our testing protocols to be inadequate;
- the appropriate authorizations are not granted on a timely basis, or at all;
- the process to obtain authorization takes longer than expected or we have insufficient funds to pursue such approvals;
- we lose previously-received authorizations; or
- we do not comply with regulatory requirements.

Medical and biopharmaceutical research and development involves the controlled use of hazardous materials, such as radioactive compounds and chemical solvents. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and waste products. In addition, we handle and dispose of human tissue. Although we believe that our safety procedures for handling these materials are adequate, if accidental contamination or injury were to occur, we could be liable for damages.

**WE RELY HEAVILY UPON OUR PATENTS AND PROPRIETARY TECHNOLOGY AND ANY FUTURE CLAIMS THAT OUR PATENTS ARE INVALID COULD SERIOUSLY HARM OUR BUSINESS**

We rely upon our portfolio of patent rights, patent applications and exclusive licenses to patents and patent applications relating to living tissue products, organ assist treatments and other aspects of tissue engineering. We currently have 26 patents issued in the US, 11 patents issued in Europe and 6 patents issued in Japan. As part of our continuing interest in protecting intellectual property rights, we have filed and are prosecuting 15 other patent applications in the US. We also license some of our technologies under an exclusive patent license agreement with the Massachusetts Institute of Technology ("MIT"). The agreement with MIT covers certain US patents and corresponding patents in Europe and Japan. The earliest patent expiration is in 2006 for the US. Pursuant to the MIT agreement, we have been granted an exclusive, worldwide license to make, use and sell the products covered by the patents and to practice the procedures covered by the patents. Additionally, we have purchased intellectual property from Baxter Healthcare Corporation related to our liver assist device program, which includes two US patents - one issued and one pending - as well as corresponding international patents. We are not currently a party in any infringement claim.

We expect to aggressively patent and protect our proprietary technologies. However, we cannot be sure that any additional patents will be issued to us as a result of our domestic or foreign patent applications or that any of our patents will withstand challenges by others. Patents issued to or licensed by us may be infringed or third parties may independently develop either the same or similar technology. Similarly, our patents may not provide us with meaningful protection from competitors, including those who may pursue patents which may prevent, limit or interfere with our products or will require licensing and the payment of significant fees or royalties by us to such third parties in order to enable us to conduct our business. We may sue or be sued by third parties regarding patents and other intellectual property rights. These suits are costly and would divert funds and management and technical resources from our operations.

We also rely upon unpatented proprietary technology, know-how and trade secrets and seek to protect them through confidentiality agreements with employees, consultants and advisors. We request that any corporate sponsor with which we enter into a collaborative agreement do so as well. If these confidentiality agreements are breached, we may not have adequate remedies for the breach. In addition, others may independently develop or otherwise acquire substantially the same proprietary technology as our technology and trade secrets.

We have relationships with a number of academic consultants who are not employed by us. Accordingly, we have limited control over their activities and can expect only limited amounts of their time to be dedicated to our activities. These persons may have consulting, employment or advisory arrangements with other entities that may conflict with or compete with their obligations to us. Our consultants typically sign agreements that provide for confidentiality of our proprietary information and results of studies. However, in connection with every relationship, we may not be able to maintain the confidentiality of our technology, the dissemination of which could hurt our competitive position and results of operations. To the extent that our scientific consultants develop inventions or processes independently that may be applicable to our proposed products, disputes may arise as to the ownership of the proprietary rights to such information, and we may not win those disputes.

#### WE MUST BE ABLE TO MANUFACTURE OUR PRODUCTS SUCCESSFULLY

The process of manufacturing our products is complex, requiring strict adherence to manufacturing protocols. We have been producing our lead product, Apligraf, for commercial sale since the second half of 1997 in adherence with these manufacturing protocols. However, with increasing demand for Apligraf, we must further transition from small-scale to full-scale production of our products. If we do not make the full-scale transition successfully, we will not be able to satisfy the demand for our products and our results of operations will be hurt.

We are required to maintain a manufacturing facility in compliance with Good Manufacturing Practices. Manufacturing facilities and processes must pass an inspection before the FDA issues any product licenses necessary to market medical therapeutics and are subject to continual review and periodic inspection. Foreign regulatory agencies can also have manufacturing controls and inspections. We may not be able to maintain the necessary regulatory approvals for our manufacturing operations or manufacture our products in a cost-effective manner. If we were unable to manufacture potential products independently or obtain or retain third party manufacturing on commercially acceptable terms, the submission of products for final regulatory approval and initiation of marketing would be delayed. This, in turn, may cause us to be unable to commercialize product candidates as planned, on a timely basis or on a profitable basis.

#### WE MUST BE ABLE TO OBTAIN ADEQUATE SOURCES OF SUPPLY

We manufacture Apligraf for commercial sale, as well as for use in clinical trials, at our Canton, Massachusetts facility. Among the fundamental raw materials needed to manufacture Apligraf are keratinocyte and fibroblast cells. Because these cells are derived from donated infant foreskin, they may contain human-borne pathogens. We perform extensive testing of the cells for pathogens, including the HIV or "AIDS" virus. Our inability to obtain cells of adequate purity, or cells that are pathogen-free, would limit our ability to manufacture sufficient quantities of our products.

Another major material required to produce our products is collagen, a protein obtained from animal source tissue. We have developed a proprietary method of procuring our own collagen that we believe is superior in quality and strength to collagen available from commercial sources. We currently obtain animal source tissue from US suppliers only. We may not be able to obtain adequate supplies of animal source tissue to meet our future needs or on a cost-effective basis. The thermo-formed tray assembly that is used in the manufacturing process of Apligraf is available to us under a supply arrangement with only one manufacturing source. Because the FDA approval process requires manufacturers to specify their proposed materials of certain components in their applications, FDA approval of a new material would be required if a currently approved material became unavailable from a supplier. If we are unable to obtain adequate supplies of thermo-formed tray assemblies to meet future Apligraf manufacturing needs or if we cannot obtain such assemblies on a cost-effective basis, our operations would be hurt.

Interruptions in our supply of materials may occur in the future or we may have to obtain alternative vendors for these materials. Any significant supply interruption would adversely affect the production of Apligraf. In addition, an uncorrected impurity or a supplier's variation in a raw material, either unknown to us or incompatible with our manufacturing process, could hurt our ability to manufacture products.

#### THE RETENTION OF KEY PERSONNEL IS IMPORTANT TO OUR COMPETITIVE POSITION

Because of the specialized nature of our business, our success will depend upon our ability to attract and retain highly qualified personnel and to develop and maintain relationships with leading research institutions. The competition for those relationships and for experienced personnel amongst the biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions is intense. If we are unable to continue to attract and retain such personnel or relationships, our competitive position could be hurt.

#### WE MAY BE SUBJECT TO PRODUCT LIABILITY SUITS; OUR INSURANCE MAY NOT BE SUFFICIENT TO COVER DAMAGES

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing, marketing and sale of medical products. The use of our products and product candidates, whether for clinical trials or commercial sale, may expose us to product liability claims or product recall and possible adverse publicity. Although we have product liability insurance coverage, the level or breadth of our coverage may not be adequate to fully cover potential liability claims. In addition, we may not be able to obtain additional product liability coverage in the future at an acceptable cost. A successful claim or series of claims brought against us in excess of our insurance coverage and the effect of product liability litigation upon the reputation and marketability of our technology and products, could negatively affect our business.

OUR BUSINESS IS SUBJECT TO THE UNCERTAINTY OF THIRD-PARTY REIMBURSEMENT AND  
HEALTH CARE REFORM MEASURES WHICH MAY LIMIT MARKET ACCEPTANCE

In both domestic and foreign markets, our ability to commercialize our product candidates will depend, in part, upon the availability of reimbursement from third-party payors, such as government health administration authorities, private health insurers and other organizations. Third-party payors are increasingly challenging the price and cost-effectiveness of medical products. If our products are not considered cost-effective, third-party payors may limit reimbursement. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA and by refusing, in some cases, to provide any coverage for uses of approved products for disease indications for which the FDA has not granted marketing approval. If government and third party payors do not provide adequate coverage and reimbursement levels for uses of our products, the market acceptance of our products would be limited.

There have been a number of federal and state proposals during the last few years to subject the pricing of pharmaceuticals to government control and to make other changes to the health care system of the US. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payors for health care goods and services may take in response to any health care reform proposals or legislation. We cannot predict the effect health care reforms may have on our business.

OUR STOCK PRICE IS VOLATILE AND CAN FLUCTUATE SIGNIFICANTLY BASED ON EVENTS  
NOT IN OUR CONTROL AND GENERAL INDUSTRY CONDITIONS

The biotechnology sector seems particularly vulnerable to abrupt changes in investor sentiment. Stock prices of companies in the biotechnology industry, including ours, can swing dramatically, with little relationship to operating performance. Our stock price may be affected by a number of factors including, but not limited to:

- clinical trial results, regulatory decisions and other product development events;
- the outcome of litigation;
- decisions relating to intellectual property rights;
- the entrance of competitive products into our market;
- changes in reimbursement policies or other practices related to the pharmaceutical industry; or
- other industry and market changes or trends.

During the past three years, the price of our common stock, adjusted for stock splits, has ranged from \$6.75 to \$35.19 per share. These fluctuations can occur due to events outside of our control, regulatory actions such as government approval of products or reimbursements, and general market conditions affecting the biotechnology sector or the stock market generally.

WE WILL NEED TO RAISE ADDITIONAL FUNDS, WHICH COULD ADVERSELY AFFECT YOUR  
INVESTMENT

Based upon our current plans, we believe existing working capital at December 31, 2000, together with the proceeds of product and other revenues in 2001 and proceeds available from exercising a portion or all of a \$20,000,000 equity security put with Novartis, which is at our discretion, will be sufficient to finance operations through at least the first quarter of 2002. We expect to raise additional funds in 2001 through equity financing. However, this statement is forward-looking and changes may occur that would significantly decrease available cash before such time. Factors that may change our cash requirements include:

- Sales volume forecasts not achieved;
- Delays in obtaining regulatory approvals of products in different countries, if needed, and subsequent timing of product launches;
- Delays in commercial acceptance and reimbursement when product launches occur;
- Changes in the progress of research and development programs; and
- Changes in the resources devoted to outside research collaborations or projects, self-funded projects, proprietary manufacturing methods and advanced technologies.

Any of these events could adversely impact our capital resources, requiring us to raise additional funds. Management believes that additional funds may be available through equity or debt financing, strategic alliances with corporate partners, capital lease arrangements, or other sources of financing in the future. There can be no assurances that these funds will be available when required on terms acceptable to us, if at all. If adequate funds are not available when needed, we would need to delay, scale back or eliminate certain research and development programs or license to third parties certain products or technologies that we would otherwise undertake ourselves, resulting in a potential adverse effect on our financial condition and results of operations.

#### OUR ANTI-TAKEOVER MEASURES MAY AFFECT THE VALUE OF OUR STOCK

We, as a Delaware corporation, are subject to the General Corporation Law of the State of Delaware, including Section 203, an anti-takeover law enacted in 1988. In general, Section 203 restricts the ability of a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder. As a result of the application of Section 203 and certain provisions in our certificate of incorporation and bylaws, potential acquirors may be discouraged from attempting to acquire us, thereby possibly depriving our stockholders of acquisition opportunities to sell or otherwise dispose of our stock at above market prices typical of such acquisitions.

We have also adopted a shareholder rights plan, which gives holders of common stock the right to purchase shares of our Series B Junior Participating Preferred Stock if a potential acquiror purchases or plans to make a tender offer to purchase 15% or more of our outstanding common stock. The existence of this plan may make it more difficult for a third party to acquire control of us.

We are authorized to issue up to 1,000,000 shares of preferred stock, \$1.00 par value per share and to determine the price, privileges and other terms of such shares. The issuance of any preferred stock with superior rights to the common stocks could reduce the value of the common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with or sell our assets to a third party, thereby preserving control of Organogenesis by present owners and management and preventing our holders of common stock from realizing a premium on their shares.

#### THE VALUE OF YOUR SECURITIES MAY DECREASE IF OTHER SECURITY HOLDERS EXERCISE THEIR OPTIONS AND WARRANTS OR CONVERT THEIR DEBT INTO COMMON STOCK

At December 31, 2000, 34,489,459 shares of our common stock are outstanding, which excludes 85,000 treasury shares. We have reserved an additional 9,583,539 shares of common stock for future issuance or conversion of stock options, warrants and the convertible debentures (excluding 1,911,075 shares of common stock remaining under a shelf registration declared effective on February 14, 2000). We plan to issue additional options in the future. If any of these securities are exercised or converted, investors may experience dilution in the market value and earnings per share of the common stock into which these securities are convertible.

## COLLABORATIVE AND OTHER AGREEMENTS

In January 1996, we entered into a collaborative agreement with Novartis granting Novartis exclusive global marketing rights to Apligraf. Under the agreement, we have received equity investments, non-refundable research, development and milestone support payments, product payments and other payments. During March 2000, we received \$5,000,000 from Novartis, which represented a support payment received in advance of achievement of a milestone related to the diabetic foot ulcer indication. In June 2000, we recognized support revenue when achievement of the milestone was met upon FDA approval of Apligraf for use in diabetic foot ulcers. The following table summarizes by year all equity investments, non-refundable research, development and milestone support payments received to date. Product and other payments are included under the captions "Product sales to related party" and "Other revenues" in our financial statements.

	1996	1997	1998	1999	2000
Equity investments	\$ 5,000,000	\$ -	\$ 6,000,000	\$ -	\$ -
Up front non-refundable research and development support payments	6,500,000	2,500,000	750,000	-	-
Non-refundable milestone payments	-	-	6,000,000	-	5,000,000
<b>Total</b>	<b>\$11,500,000</b>	<b>\$ 2,500,000</b>	<b>\$12,750,000</b>	<b>\$ -</b>	<b>\$ 5,000,000</b>

During February 2001, we amended our collaborative agreement with Novartis, effective January 2, 2001. The amended agreement:

- Grants Novartis the right to purchase an exclusive option to negotiate terms to license Organogenesis's product Vitrix, soon to commence human pivotal trials, and also for a second living dermal replacement product currently in Organogenesis research;
- Provides Organogenesis with significantly higher payments for units of Apligraf;
- Grants Organogenesis the right for three years to sell, at its discretion, to Novartis up to \$20 million in equity;
- Includes funding support from Novartis to upgrade Organogenesis's manufacturing facility and for the facility investment needed for approval and sale of Apligraf in the European Union;
- Includes funding support for Apligraf clinical development activities (e.g., to further broaden its approved uses); and
- Includes development funding support for each living dermal replacement product for which Novartis purchases an option to commence licensing negotiations.

We supply Novartis's global requirements for Apligraf and receive a product payment based on net product sales.

In 1994, we signed a license agreement with Toyobo Ltd. granting Toyobo a license to manufacture and market TestSkin(TM) in Japan in exchange for royalty payments. Additionally, Toyobo may, but is not obligated to, purchase collagen and other products from us. Revenues under this arrangement are included in other revenues and are not significant. This agreement is coterminous with certain patents.

## RESEARCH AGREEMENTS

We have entered into various collaborative research agreements that are generally funded over a one or two-year period. Each agreement is reviewed at least annually and the amounts to be funded for the next period are then determined. Either party may cancel the agreement upon advance written notice. Total payments made by us to third parties under these agreements were \$648,000, \$662,000 and \$542,000 for 1998, 1999 and 2000, respectively. All our research agreements are early stage today, but have the potential to develop into more material relationships in the future.

Testskin(TM) is a trademark of Organogenesis.

## RESEARCH AND DEVELOPMENT

We plan to continue to focus product development efforts on high-quality cell therapy and connective tissue scaffolds for use in a variety of areas, including wound care, surgery, cardiovascular medicine and liver disease.

Our research and development staff consists of scientists and laboratory assistants with technical expertise in cell and developmental biology, engineering, chemistry, immunology, cryopreservation, molecular biology and clinical medicine.

For 1998, 1999 and 2000, research and development expenses were \$17,542,000, \$19,066,000, and \$17,511,000, respectively, which consist of costs associated with research, development, clinical and process development, facilities and engineering support used in R&D. All amounts expended were for company-sponsored research and development.

## EMPLOYEES

As of March 5, 2001, we had 236 full-time employees, inclusive of: 134 in Operations; 67 in Research and Clinical; and 35 in General and Administrative. In total we have 15 employees with PhDs. We have established a stock option plan providing equity incentives, an employee stock purchase plan and a 401(k) plan for all full-time employees. We believe that, through equity participation, attractive fringe benefit programs and the opportunity to contribute to the development and commercialization of new products using new technology, we will continue to be able to attract highly-qualified personnel.

## SCIENTIFIC ADVISORY BOARD

We have a Scientific Advisory Board ("SAB") composed of five physicians, professors and scientists in various fields of medicine and science. The SAB meets from time to time to advise and consult with management and our scientific staff. Each member of the SAB is expected to devote only a portion of his time to us and may have consulting or other advisory arrangements with other entities that may conflict or compete with his obligations to us. Members of the SAB have no formal duties, authority or management obligations.

## Item 2. PROPERTIES

We occupy our main office and manufacturing premises under a facility lease for 79,500 square feet of space in Canton, Massachusetts at an annual average base rent of approximately \$790,000, plus operating expenses, that expires on September 30, 2004. This lease has three options to extend the term for an additional five years per option. Taxes, insurance and operating expenses are our responsibility under the terms of the lease. In May 1999, we entered into another facility lease for approximately 62,500 square feet of additional office and warehouse space in Canton, Massachusetts. In June 2000, we amended this lease to terminate 42,000 square feet, leaving 20,500 square feet remaining at an annual average base rent of approximately \$138,500, plus operating expenses, that expires on December 5, 2004. This lease has three options to extend the term for an additional five years per option. In total, we currently lease 100,000 square feet of space.

We believe that current facilities will adequately support manufacturing needs and research and development activities through the end of 2001 and beyond.

ITEM 3. LEGAL PROCEEDINGS

None

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None

## PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on the American Stock Exchange under the symbol ORG. On March 5, 2001, there were 786 shareholders of record of our common stock. The table below lists the high and low quarterly range of reported closing prices of our common stock during the past two years.

	1999		2000	
	High	Low	High	Low
First Quarter	\$15.69	\$10.94	\$19.50	\$ 8.00
Second Quarter	13.75	8.75	12.69	8.25
Third Quarter	11.56	7.50	16.27	11.11
Fourth Quarter	11.88	6.75	13.81	6.80

On March 28, 2001, the last sale price of the common stock was \$8.26.

We have never paid any cash dividends on our common stock. We currently intend to retain all future earnings, if any, for use in our business and do not expect to pay any cash dividends in the foreseeable future. As a result, an investor will only recognize an economic gain on an investment in our stock from an appreciation in the price of our stock. Under our term loan, we are restricted from paying cash dividends until the loans are fully repaid.

## ITEM 6. SELECTED FINANCIAL DATA (IN THOUSANDS, EXCEPT PER SHARE DATA AND NUMBER OF EMPLOYEES)

The selected financial data set forth in the table below is not necessarily indicative of our results of future operations and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and related notes included in item 7.

	For the Years Ended December 31,				
	1996	1997	1998	1999	2000
Revenues	\$ 6,542	\$ 3,029	\$ 7,939	\$ 2,676	\$ 10,240
Net Loss	(7,499)	(19,807)	(14,031)	(28,350)	(28,605) (1)
Net Loss Per Common Share	(0.27)	(0.70)	(0.48)	(0.93)	(0.85) (1)
Working Capital	11,256	4,843	15,541	2,981	6,226
Capital Expenditures	3,311	1,069	2,464	5,767	3,397
Total Assets	22,436	13,780	26,710	27,305	27,872
Total Long-Term Debt	-	-	-	22,287	18,835
Stockholders' Equity (Deficit)	18,478	11,523	23,239	(6,974)	(3,784)
Number of Employees	115	137	186	208	232
PRO FORMA AMOUNTS ASSUMING SAB 101 IS APPLIED RETROACTIVELY:					
Revenues	545	1,344	8,222	3,733	
Net Loss	(13,496)	(21,492)	(13,748)	(27,293)	
Net Loss Per Common Share	(0.49)	(0.76)	(0.47)	(0.90)	

(1) Includes the cumulative effect of a change in accounting principle related to all up front non-refundable research and development support payments recognized in prior periods of \$6,342,000 or \$0.19 per share (basic and diluted) for 2000, in accordance with SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101).

## Item 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

## Overview of Organogenesis Inc.

Organogenesis Inc. - a tissue engineering company - designs, develops and manufactures medical products containing living cells and/or natural connective tissue. We are the developer and manufacturer of the only mass-produced product containing living human cells to gain FDA marketing approval. Our product development focus includes living tissue replacements, a cell-based organ assist device and other tissue-engineered products.

## OUR LEAD PRODUCT, APLIGRAF

Our lead product, Apligraf living skin substitute, gained FDA marketing approval for use in the treatment of healing-resistant venous leg ulcers in 1998. In June 2000, Apligraf was approved for use in the treatment of healing-resistant diabetic foot ulcers. Novartis Pharma AG ("Novartis") has exclusive global Apligraf marketing rights. In addition to being marketed in the US, Apligraf is also available in select international markets. Novartis expects to submit for marketing approval across the European Union in the Spring of 2001.

## OUR PIPELINE

Our research and development pipeline includes a living dermal replacement product candidate, Vitrix, which we anticipate beginning human pivotal clinical trials in Spring 2001, a coronary vascular graft and a liver assist device. Additionally, a business unit - Technology Ventures - has been formed to commercialize, through partnerships and distributorships, our engineered collagen and conditioned medium technologies.

## RESULTS OF OPERATIONS

We are currently at low volume production as Apligraf has, to date, shown a gradual ramp-up in sales. We expect production costs to exceed product sales for at least the next 18 months due to the high costs associated with low volume production. We expect production volume to increase due to recent Medicare progress with coverage for Apligraf, FDA approval of Apligraf for use in diabetic foot ulcers and expanded Novartis sales and marketing support.

## REVENUES

SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101), was issued in December 1999 and summarizes certain of the Staff's views in applying generally accepted accounting principles to revenue recognition in financial statements. We adopted SAB 101 in the fourth quarter of 2000, effective January 1, 2000, and recorded a cumulative effect of a change in accounting principle related to all up front non-refundable research and development support payments recognized in prior periods of \$6,342,000. Of this amount, \$1,057,000 was recognized as revenue in 2000, and the remainder will be recognized ratably through December 2005, in accordance with SAB 101's guidance.

Total revenues for the years 1998, 1999 and 2000 consisted of:

	1998	1999	2000
Research, development and milestone support from related party	\$6,750,000	\$ -	\$ 6,057,000
Product sales to related party	1,082,000	1,844,000	2,957,000
Research and development grants	-	101,000	1,065,000
Other revenues	107,000	731,000	161,000
	\$7,939,000	\$2,676,000	\$10,240,000

In 2000, research, development and milestone support from related party of \$6,057,000 includes a \$5,000,000 milestone payment related to the diabetic foot ulcer indication and \$1,057,000 of deferred revenue recognized in the current year. No such revenues were earned in 1999. In 1998, we received

\$6,750,000 of payments primarily related to the venous leg ulcer indication. The increase in product sales to related party over the last three years is due to increased unit sales of Apligraf to Novartis. We expect Apligraf commercial sales to continue to increase. Research and development grants revenue increased primarily due to a full year of grant work performed during 2000 compared to one month performed during 1999 and no grants in 1998 (refer to the grant section under the "Commitments" footnote to the Financial Statements for a full description). Other revenues decreased in 2000 and increased in 1999, primarily due to changes in the level of Novartis funding for publication study programs. Total revenues for the years 1998 and 1999 have not been adjusted for the adoption of SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements".

#### COSTS AND EXPENSES

**Cost of product sales to related party:** Our cost of product sales was \$6,421,000 in 2000, compared to \$3,773,000 in 1999. These expenses increased due to higher unit sales of Apligraf to Novartis and a higher amount of fixed costs due to infrastructure increases needed to support anticipated future higher unit volume levels. Cost of product sales includes the direct costs to manufacture and package Apligraf and an allocation of our production-related indirect costs. All costs of production prior to 1999 were included in research and development expense due to insignificant commercial sales and low production volume associated with early stage commercialization. Cost of product sales exceeded product sales due to the high costs associated with low volume production. We expect production volume to increase and our margins to improve in 2001. We expect that we will have to revise standard costs and the allocation of costs to product sales in the future as we continue to modify our manufacturing processes.

**Research and development:** Research and development expenses ("R&D") consist of costs associated with research, development, clinical, process development, facilities and engineering support excluding the allocation of our production related indirect costs. These expenses decreased to \$17,511,000 for 2000 from \$19,066,000 in 1999 and \$17,542,000 in 1998. The decrease in 2000 versus 1999 was primarily due to: a decrease in clinical-related costs due to completion of the Apligraf diabetic foot ulcer pivotal trial partially off-set by an increase in operations support for supplies, personnel costs; and increases in depreciation expense on significant leasehold improvements put into service during 2000. The increase in 1999 versus 1998 was primarily due to: an increase in personnel costs, outside services, supplies, and occupancy costs to support our ongoing programs, including Vitrix and the liver assist device; and costs to support publications studies and other sponsored programs. This was partially off-set by a decrease in clinical-related costs because 1998 included non-recurring expenses related to FDA approval and because the Apligraf diabetic foot ulcer pivotal trial was at its peak, and by a decrease in operating-related expenditures. Process development, facilities and engineering support expenses included in research and development were \$8,001,000, \$7,305,000 and \$7,160,000 for the periods 2000, 1999 and 1998, respectively. We expect that our R&D expenses will increase moderately during 2001.

Included in R&D for 1999 is a non-cash charge of \$900,000 relating to the purchase of incomplete technology to be used specifically in our liver assist device research and development efforts (refer to the "Commitments" footnote to the Financial Statements for a full description of this technology). The purchase was made to strengthen our resources and intellectual property position. The charge to expense was due to the early stage of the technology that had not provided proof of principle. Additionally, the time and cost to prove this principle was not known. We expect it will cost millions of dollars and take a minimum of 4 to 6 years before we could develop a product which might be approved for commercial sale. It is our intent that if proof of principle is established, we will seek a partnership for this project.

**General and administrative expenses:** General and administrative expenses ("G&A") include the costs of our corporate, finance, information technology and human resource functions. These expenses were \$7,638,000 for 2000, \$7,808,000 for 1999 and \$5,486,000 for 1998. The 2000 decrease was primarily due to decreased personnel costs and professional service fees. The 1999 increase from \$5,486,000 in 1998 was primarily due to personnel additions and increased outside professional fees; occupancy costs and consolidating administrative facilities; and the estimated fair value of warrants issued relating to a consulting contract. We expect that our G&A expenses will decrease during 2001 as we expect to use less outside services.

**Other Income and Expense:** Interest income increased primarily due to the increase in funds available for investment. Interest expense increased to \$2,092,000 for 2000 compared to \$1,281,000 in 1999, primarily due to a full year of convertible debenture and term loan interest in 2000 compared to 1999. Interest expense was \$1,281,000 for 1999 due to the issuance of convertible debentures in March 1999.

**Net Loss:** We incurred a net loss before cumulative effect of change in accounting principle of \$22,263,000 or \$0.66 per share (basic and diluted) and a net loss effected for the change in accounting principle of \$28,605,000 or \$0.85 per share (basic and diluted) for 2000, compared to a net loss of \$28,350,000 or \$0.93 per share (basic and diluted) for 1999 and a net loss of \$14,031,000 or \$0.48 per share (basic and diluted) for 1998.

**Cumulative effect of change in accounting principle:** SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101), was issued in December 1999 and summarizes certain of the Staff's views in applying generally accepted accounting principles to revenue recognition in financial statements. We adopted SAB 101 in the fourth quarter of 2000, effective January 1, 2000, and recorded a cumulative effect of a change in accounting principle related to all up front non-refundable research and development support payments recognized in prior periods of \$6,342,000 or \$0.19 per share (basic and diluted) for 2000, with a corresponding increase to deferred revenue which will be recognized in future periods. The impact of adopting SAB 101 is not reflected in the amounts presented in the Results of Operations for the years ended December 31, 1999 and 1998. See financial statements and related notes for additional details related to this change in accounting principle.

#### Liquidity and Capital Resources

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##### FUNDS USED IN OPERATIONS

At December 31, 2000, we had cash, cash equivalents and investments in the aggregate amount of \$12,183,000 and working capital of \$6,226,000, compared to \$12,439,000 and \$2,981,000, respectively, at December 31, 1999. Working capital increased in 2000 due primarily to the excess of financings over operating cash flows. Cash equivalents consist of money market funds, which are highly liquid and have original maturities of less than three months. Investments consist of securities that have an A or A1 rating or better with a maximum maturity of two years. Cash used in operating activities was \$18,482,000 in 2000, compared to \$23,650,000 in 1999, primarily for financing our ongoing research, development and manufacturing operations, offset by \$5,000,000 cash received from Novartis in 2000 for achievement of a milestone related to the diabetic foot ulcer indication.

#### CAPITAL SPENDING

Capital expenditures were \$3,397,000 and \$5,767,000 during 2000 and 1999, respectively, primarily related to the further build-out of existing facilities to support Apligraf manufacturing, as well as the acquisition of equipment for research and development programs and manufacturing. We will continue to utilize funds during 2001 to expand our existing facility in the areas of Apligraf manufacturing, packaging and other process development improvement programs, including funds which we will receive from Novartis to upgrade our manufacturing facility and for the facility investment needed for approval and sale of Apligraf in the European Union.

#### NOVARTIS SUPPORT PAYMENTS

During March 2000, we received \$5,000,000 from Novartis, which represented a support payment received in advance of achievement of a milestone related to the diabetic foot ulcer indication. In June 2000, we recognized support revenue when achievement of the milestone was met upon FDA approval of Apligraf for use in diabetic foot ulcers. We did not receive any support payments from Novartis in 1999 and received equity and support payments totaling \$12,750,000 in 1998. (Refer to the "Related Party Transactions and Other Agreements" footnote to the Financial Statements for a full description).

#### FINANCING

From inception, we have financed our operations substantially through private and public placements of equity securities and convertible debt, as well as the receipt of research, development and milestone support payments and contract revenues, interest income from investments, sale of products and receipt of royalties. During 2000, financing activities provided cash of \$21,623,000 primarily from the sale of common stock that generated net proceeds of \$15,930,000 and the exercise of stock options that generated \$12,267,000, partially offset by the redemption of Series C redeemable convertible preferred stock in cash for \$6,180,000 and payment of a term loan for \$394,000. Financing activities provided cash of \$24,015,000 during 1999 from: the sale of convertible debentures and warrants to purchase common stock that generated net proceeds of \$19,425,000; the issuance of a term loan that generated proceeds of \$4,728,000 and the exercise of stock options of \$813,000, offset by the purchase of treasury stock totaling \$951,000.

During March 2000, we redeemed in cash 62 shares of Series C convertible preferred stock representing all outstanding shares of Series C convertible preferred stock, for approximately \$6,180,000.

On February 14, 2000, the Securities and Exchange Commission declared effective a shelf registration for the placement of up to 3,000,000 shares of common stock with an aggregate offering price not to exceed \$50,000,000. In February and March 2000, we completed private placements for 1,088,925 shares of common stock under this shelf registration yielding net proceeds of approximately \$15,930,000.

In December 2000, the Board of Directors authorized a common stock repurchase program for up to 500,000 additional shares. Subsequent to December 31, 2000, we repurchased 165,000 shares of common stock for an aggregate purchase price of approximately \$1,367,000. The stock repurchase program may be discontinued at any time.

**LIQUIDITY**

Based upon our current plans, we believe existing working capital at December 31, 2000, together with the proceeds of product and other revenues in 2001 and proceeds available from exercising a portion or all of a \$20,000,000 equity security put with Novartis, which is at our discretion, will be sufficient to finance operations through at least the first quarter of 2002. We expect to raise additional funds in 2001 through equity financing. However, this statement is forward-looking and changes may occur that would significantly decrease available cash before such time. Factors that may change our cash requirements include:

- Sales volume forecasts not achieved;
- Delays in obtaining regulatory approvals of products in different countries, if needed, and subsequent timing of product launches;
- Delays in commercial acceptance and reimbursement when product launches occur;
- Changes in the progress of research and development programs; and
- Changes in the resources devoted to outside research collaborations or projects, self-funded projects, proprietary manufacturing methods and advanced technologies.

Any of these events could adversely impact our capital resources, requiring us to raise additional funds. Management believes that additional funds may be available through equity or debt financing, strategic alliances with corporate partners, capital lease arrangements, or other sources of financing in the future. There can be no assurances that these funds will be available when required on terms acceptable to us, if at all. If adequate funds are not available when needed, we would need to delay, scale back or eliminate certain research and development programs or license to third parties certain products or technologies that we would otherwise undertake ourselves, resulting in a potential adverse effect on our financial condition and results of operations.

**TAXES**

At December 31, 2000, we had federal net operating loss and tax credit carryforwards of approximately \$139,955,000 and \$3,769,000, and state net operating loss and tax credit carryforwards of approximately \$91,139,000 and \$2,648,000. These losses and tax credits are available to reduce federal and state taxable income and income taxes, respectively, in future years, if any. However, the realizability of deferred tax assets is not assured as it depends upon future taxable income. Accordingly, we have recorded a 100% valuation allowance against these assets. We are required to recognize all or a portion of net deferred tax assets, with corresponding increases to net income, when we believe, given the weight of all available evidence, that it is more likely than not that all or a portion of the benefits of net operating loss carryforwards and other credits will be realized. However, there can be no assurance that we will ever realize any future cash flows or benefits from these losses and tax credits. Ownership changes, as defined in internal revenue code, may result in future limitations on the utilization of net operating losses and research and development tax credit carryforwards that can be utilized annually to offset future taxable income.

**IMPACT OF INFLATION**

Although it is difficult to predict the impact of inflation on our costs and revenues in connection with our products, we do not anticipate that inflation will materially impact our costs of operation or the profitability of our products when marketed.

**Impact of New Accounting Pronouncement**

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In June of 1998, the FASB issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities", which establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities. We will adopt SFAS No. 133 as required by SFAS No. 137, "Deferral of the Effective Date of SFAS No. 133" in 2001. To date, we have not utilized derivative instruments or hedging activities and, therefore, the adoption of SFAS No. 133 is not expected to have a material impact on our financial position or results of operations.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The exposure of market risk associated with risk-sensitive instruments is not material, as our sales are transacted primarily in United States dollars, invest primarily in money market funds and have not entered into hedging transactions.

## Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ORGANOGENESIS INC.

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements included in Item 8:

Report of Independent Accountants.....	23
Consolidated Balance Sheets as of December 31, 1999 and 2000.....	24
Consolidated Statements of Operations For the Years Ended December 31, 1998, 1999 and 2000.....	25
Consolidated Statements of Cash Flows For the Years Ended December 31, 1998, 1999 and 2000.....	26
Consolidated Statements of Changes in Stockholders' Equity For the Years Ended December 31, 1998, 1999 and 2000.....	27
Notes to Consolidated Financial Statements.....	28

Report of Independent Accountants

To the Board of Directors and Stockholders of Organogenesis Inc.:

In our opinion, the accompanying consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Organogenesis Inc. and its subsidiaries at December 31, 2000 and 1999, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2000 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in the notes to the consolidated financial statements, during the year ended December 31, 2000 the Company changed its method of recognizing revenue.

PricewaterhouseCoopers LLP

Boston, Massachusetts  
March 13, 2001

## ORGANOGENESIS INC.

CONSOLIDATED BALANCE SHEETS  
(In thousands, except share and per share data)

	At December 31,	
	1999	2000
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 5,727	\$ 9,539
Investments	6,712	2,644
Inventory	906	1,377
Receivable from related party	985	501
Other current assets	643	758
Total current assets	14,973	14,819
Property and equipment, net	11,731	12,608
Other assets	601	445
<b>Total Assets</b>	<b>\$ 27,305</b>	<b>\$ 27,872</b>
<b>Liabilities</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,378	\$ 2,378
Accrued expenses	3,438	3,582
Current portion of term loan	394	1,576
Deferred revenue	--	1,057
Other current liabilities	602	--
Series C convertible preferred stock	6,180	--
Total current liabilities	11,992	8,593
Deferred revenue		4,228
Long-term convertible debt	17,953	16,077
Term loan	4,334	2,758
<b>Commitments (see Notes)</b>		
<b>Stockholders' Deficit</b>		
Common stock, par value \$.01; authorized 80,000,000 shares:		
Outstanding 30,604,019 and 34,489,459 shares at		
December 31, 1999 and 2000, respectively	307	346
Additional paid-in capital	122,890	154,646
Accumulated deficit	(129,367)	(157,972)
Treasury stock at cost, 85,000 shares at		
December 31, 1999 and 2000	(804)	(804)
Total stockholders' deficit	(6,974)	(3,784)
<b>Total Liabilities and Stockholders' Deficit</b>	<b>\$ 27,305</b>	<b>\$ 27,872</b>

The accompanying notes are an integral part of the consolidated financial statements.